REMARKS

Claims 34-36 and 46-66 are pending in this application. Claims 49-66 are new. The new claims are directed to a method of producing an immunogenic composition comprising a virus or a viral antigen, which falls under the elected restriction Group XI, as set forth by the examiner. Supports for the new claims can be found throughout the specification, for example, see page 3 paragraph [13] through page 5 paragraph [17], page 6 paragraph [23] through page 7 paragraph [26], and page 11 paragraph [37] through page 16 paragraph [51]. Therefore, no new matter is introduced. The Office Action is discussed below:

Claim Rejection under 35 USC § 103:

On pages 2-5 of the office action, the examiner has maintained the rejection of claims 34-36 and 46-48 and alleged as being unpatentable over Shibuya *et al.* (US Patent No. 6,406,909) in view of Kistner *et al.* (US Patent No. 5,753,489), Quest International Product Information, Norwich, NY, 1995 and Sheffield Pharma.

In response to the arguments filed on August 7, 2007, on page 5 of the Office Action, the examiner opines regarding Shibuya's Basal Medium composition and the components as listed in Table 1, that the listed "human insulin as an ingredient of medium" is only an example, thus maintained the rejection. Applicants disagree with the examiner and point out that the examiner has not comprehended that Table 1 is only an example for the "amounts" of each components of the basal medium, while the components remain as listed therein. Applicants refer to Shibuya column 5, lines 33-36 that clearly describes that:

"Specific examples of the amounts of addition of various nutrient components as the basal medium components are shown in Table 1."

Applicants point out that the Shibuya disclosure has no provision to exclude "Insulin Human Recombinant" as a component of the basal medium, as listed in Table 1.

Applicants believe that the examiner is confused with the definition of "serum-free medium" as relied upon by Shibuya, which does not exclude "Insulin Human Recombinant" (see Shibuya col. 5, lines 8-10, and 23-27). Shibuya's "serum-free medium" by definition includes the basal medium composition (for example, Table 1), which includes "various peptide hormones and growth factor proteins that are not directly separated from animals, i.e., includes animal proteins that are produced with recombinant techniques,...." (see Shibuya col. 5, lines 23-27). That is, Shibuya "serum-free medium" does not include animal proteins that are directly separated from animals but includes recombinantly-produced animal proteins, such as "Insulin Human Recombinant", as discussed above.

In contrast, as noted in the response filed on August 7, 2007, by definition, the instantly claimed "serum-free medium" does not encompass recombinantly-produced animal proteins. To recapitulate, applicants reiterate that:

The claimed methods avoid animal proteins, whereas the media disclosed by Shibuya *et al.* employ animal proteins. The instant specification clearly describes that the:

> "....medium that is not supplemented with proteins and protein components from higher multicellular non-plant eukaryotes (that is, vertebrates), that possess the secondary, tertiary and quaternary structures characteristic of the proteins as they occur in nature. Typical proteins that are avoided are those found in serum and serum derived substances, such as albumin, transferrin, insulin and other growth factors. Recombinantly-produced versions of animal proteins, which can contain immunogenic bacterial components, also are avoided according to the invention, and are not present in the animal protein free medium of the invention."

See specification, for example, paragraph [28] bridging pages 7 and 8. As such, no animal proteins are added for the purposes of cell growth or maintenance.

Moreover, the "animal protein free" medium of Shibuya does not disclose the

claimed "animal protein free" medium, because the medium or the method disclosed by Shibuya *et al.* is not "animal protein free" in accordance with the instant definition of the term "animal protein free" medium. Therefore, Shibuya does not disclose an "animal protein free" medium as used in the claimed methods.

Regarding Shibuya *et al.,* on page 5 of the Office Action, the examiner also asserts "in fact, in the growth medium for the data shown in Fig. 8, no insulin is present" and opines that "the medium used for cell growth in the experiment of Fig. 8 does not have any animal derived component." Applicants disagree with the examiner's interpretation of the Shibuya disclosure and Figure 8. Applicants point out that Shibuya's Figure 8 clearly indicates that the experiment was carried using a medium containing various amounts of insulin. However, the experiment also included a control medium that contains no insulin to observe the effect of the amount of insulin on the yield of a recombinant protein (see Shibuya col. 3, lines 55-65 and Figures 7a, 7a, 8a and 8b). The data shown in Figures 7 and 8 are further clarified by Shibuya that "4 different conditions were used as regards the amount of addition of the recombinant human insulin" (see Shibuya Col. 15, lines 43-45 and lines 39-60 for additional clarification regarding the effect of various amounts of insulin). The data clearly indicate that insulin is essential for the Shibuya's medium, as shown in Figures 7 and 8, which indicate a drop in cellular growth and production of recombinant protein in absence of insulin (see "0X insulin", as shown in Figures 7 and 8). Shibuya observed some growth and production of the recombinant protein in absence of insulin (see "0X insulin", as shown in Figures 7 and 8), which are "attributable to the fact that the seeded cells were pre-cultured in a medium containing a recombinant human insulin" (see Shibuya's clarification at col. 15, lines 56-59).

Therefore, insulin was included in the growth medium for the data shown in Figure 8 and the medium used for cellular growth in the experiment resulting in Figure 8 does contain recombinant animal protein.

On pages 5-8 of the office action, the examiner also has maintained the rejection of claims 34-38 and 46-48 and alleged as being unpatentable over Price *et al.* (WO 98/15614) in view of Kistner *et al.* (US Patent No. 5,753,489), Quest International

Product Information, Norwich, NY, 1995 and Sheffield Pharma.

In response to the arguments filed on August 7, 2007, on page 8 of the Office Action, the examiner asserts that although Price *et al.* disclose that certain components are derived from animal cells, the reference discloses that these components may be added, but does not disclose that they are necessarily present. Therefore, the examiner believes that the reference does disclose the animal protein free medium as one possible culture medium. Applicants respectfully disagree with the examiner and point out that the examiner has not indicated where in the Price *et al.* such statement can be found. Applicants believe that the examiner meant to refer to page 13, line 5 of the Price disclosure, wherein the term "may be" is used. Applicants respectfully disagree with the examiner and point out that the Price disclosure used the term "may be" ambiguously throughout the disclosure, more specifically, even for the key aspect of the disclosure. Applicants refer to the Price disclosure, for example, see page 7, lines 21-24, that states "The medium of the invention may be used to culture a variety of animal cells....", whereas the title or the field of the Price *et al.* invention is directed to animal cell culture medium. Most importantly, the Price disclosure teaches away from the claimed invention by motivating one skilled in the art to use culture media containing animal proteins (see Price disclosure, for example, page 8, lines 4-10, page 13, lines 5-25; page 20, lines 17-21). In this context, applicants refer the examiner to the MPEP § 2141.02 (VI) that:

> "PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS
>
> A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)...."
>
> See MPEP § 2141.02 (VI) at 2100-124 (Rev. 5, August 2006).

In contrast, applicants point out that the claimed method requires that an "animal protein free" medium be used. Therefore, Price disclosure teaches away from the claimed invention, and does not motivate one skilled in the art to use an "animal protein

free" medium in a method in combination with other cited references to arrive at the claimed invention.

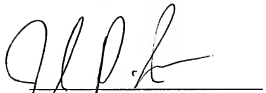
Applicants further refer the examiner to all the clarifications, facts and arguments filed on August 7, 2007, and submit that Shibuya *et al.* and Price *et al.* do not disclose the claimed invention. Applicants reiterate that any medium prepared based on the basal medium of Shibuya or Price contain animal proteins for cellular growth or maintenance. Kistner *et al.* (US Patent No. 5,753,489), Quest International Product Information, and/or the technical literature from Sheffield Pharma, do not rectify the deficiencies of Shibuya *et al.* and Price *et al.*, as discussed above. Therefore, a combination of Shibuya and/or Price and Kistner, Quest International Product Information and/or the technical literature from Sheffield Pharma does not make the claimed inventions obvious.

In view of the above, applicants request the withdrawal of the obviousness rejection.

REQUEST

Applicants submit that claims 34-38 and 46-66 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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